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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,618	07/17/2003	George W. Muller	1129-178.111111 US	2627
7590 09/10/2004				
Nicholas J. DiCeglie, JR Pennic & Edmonds, LLP 1155 Avenue of the Americas New York, NY 10036-2711		EXAMINER ANDERSON, REBECCA L		
		ART UNIT PAPER NUMBER 1626		

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/622,618	Applicant(s) MULLER ET AL.	
	Examiner Rebecca L Anderson	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 8-11, 13-15, 19-22, 24-26, 30-33 and 35-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 12, 16-18, 23, 27-29, 34 and 38-40 is/are rejected.
- 7) ☒ Claim(s) 1-5, 7, 12, 16-18, 23, 27-29 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/13/03</u> | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

Claims 1-40 are currently pending in the instant application. Claims 1-5, 7, 12, 16-18, 23, 27-29 and 34 are objected to as containing non-elected subject matter, claims 8-11, 13-15, 19-22, 24-26, 30-33 and 35-37 are withdrawn as being for non-elected subject matter and claims 1-7, 12, 16-18, 23, 27-29, 34 and 38-40 are rejected.

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-7, 12, 16-18, 23, 27-29, 34 and 38-40 and the further election of 3-(3,4-dimethoxy phenyl)-3-(3',5'-dimethoxyphenyl)acrylonitrile in the reply filed on 21 June 2004 is acknowledged. The traversal is on the ground(s) that a single search directed to a compound of formula I would necessarily encompass all of the claims in Groups I and II and would not impose an unreasonable burden on the examiner. This is not found persuasive because the inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Applicants election of Group I and the further election of of 3-(3,4-dimethoxy phenyl)-3-(3',5'-dimethoxyphenyl)acrylonitrile has resulted in the following elected invention for search and examination.

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The **elected invention for search and examination** is the products of the formula (I) wherein:

**R1** is selected from the group consisting of any alkyl of up to 10 carbon atoms, any monocycloalkyl of up to 10 carbon atoms, any polycycloalkyl of up to 10 carbon atoms, and any benzocyclic alkyl of up to 10 carbon atoms;

**R2** is hydrogen, nitro, cyano, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl, acetoxyl, carboxyl, hydroxyl, amino, lower alkyl, lower alkoxy, or halo;

**R3** is (i) phenyl unsubstituted or substituted with 1 or more substituents selected independently from the group consisting of a nitro, cyano, a halo, a trifluoromethyl, a carbethoxy, a carbomethoxy, a carbopropoxy, an acetyl, a carbamoyl, a carbamoyl substituted with an alkyl of 1 to 3 carbon atoms, an acetoxyl, a carboxyl, a hydroxyl, an amino, an amino substituted with an alkyl of 1 to 4 carbon atoms, an alkyl or cycloalkyl of 1 to 10 carbon atoms, and an alkoxy or cycloalkoxy of 1 to 10 carbon atoms, or (ii) a phenyl substituted with 1 or more substituents each selected independently from the group consisting of an alkylidenemethyl of up to 10 carbon atoms, a cycloalkylidenemethyl of up to 10 carbon atoms, a phenyl, and a methylenedioxy; and **X** is -O-.

The compounds falling outside the elected invention as identified supra are directed to nonelected subject matter and are withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). The remaining subject matter of claims 1-5, 7, 12, 16-18, 23, 27-29 and 34 that is not drawn to the above elected invention and the subject matter of claims 8-11, 13-15, 19-22, 24-26, 30-33 and 35-37 stands withdrawn under 37

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CFR 1.142(b) as being for non elected subject matter. The remaining products of claims 1-5, 7, 12, 16-18, 23, 27-29 and 34 which are not within the elected independent invention, which are independent and distinct from the elected independent invention and do not have unity with the elected compound and therefore are withdrawn by means of a restriction requirement within the claims are, for example, the compounds of the formula (I) wherein: X is  $-(C_nH_{2n})-$  or  $-CH=$ , R<sub>3</sub> is (i) naphthyl, (iii) cycloalkyl of 4 to 10 carbon atoms or (iv) pyridine, substituted pyridine, pyrrolidine, imidazole, or thiophene.

The above mentioned withdrawn compounds of the formula (I) which are withdrawn from consideration as being for non elected subject matter differ materially in structure and composition from compounds of the elected independent invention. The withdrawn compounds differ from those of the elected invention such as by a furanyl, pyridyl, imidazole, etc., which are chemically recognized to differ in structure and function as can be seen by the varying classification in the US classification system, i.e., class 546 subclass 1(+) (pyridyl), class 548 subclass 300.1(+) (imidazole) This recognized chemical diversity of the compounds can be seen by the various classification of these products in the U.S. classification system as shown above. Therefore, again, the compounds of the formula (I), which are withdrawn from consideration as being for non elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. These withdrawn compounds of the formula (I) are independent and distinct from the

elected independent invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: the nitrogen (N) of the cyano (C=N) group of the compound of the formula (I) is missing from the claim. Appropriate correction is required.

Claims 1-5, 7, 12, 16-18, 23, 27-29 and 34 are objected to as containing non-elected subject matter, for example, wherein X is  $-(C_nH_{2n})-$  or  $-CH=$ , R<sub>3</sub> is (i) naphthyl, (iii) cycloalkyl of 4 to 10 carbon atoms or (iv) pyridine, substituted pyridine, pyrrolidine, imidazole, or thiophene.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 18 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Groundwater et al. Groundwater et al. discloses the compound 11c, 3,3-bis(3-methoxyphenyl)-2-propenenitrile, in Table 3, page 7960, with molecular formula C<sub>17</sub>H<sub>15</sub>NO<sub>2</sub>, which corresponds to applicants instantly claimed compound wherein R<sub>2</sub> is a lower alkoxy (specifically a methoxy), wherein R<sub>1</sub> is an alkyl (specifically a methyl), X is  $-O-$  and R<sub>3</sub> is phenyl substituted with an alkoxy (specifically 3-methoxyphenyl).

Compound 11 c is prepared from the corresponding compound 10c, 3,3-dimethoxybenzophenone, page 7959, by the process of scheme 2, page 7953.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7, 18 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 5,929,117. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants instant claims 1-5, 7, 18 and 29 claim

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compounds wherein **R1** is selected from the group consisting of any alkyl of up to 10 carbon atoms, any monocycloalkyl of up to 10 carbon atoms, any polycycloalkyl of up to 10 carbon atoms, and any benzocyclic alkyl of up to 10 carbon atoms; **R2** is hydrogen, nitro, cyano, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl, acetox, carboxy, hydroxy, amino, lower alkyl, lower alkoxy, or halo; **R3** is (i) phenyl unsubstituted or substituted with 1 or more substituents selected independently from the group consisting of a nitro, cyano, a halo, a trifluoromethyl, a carbethoxy, a carbomethoxy, a carbopropoxy, an acetyl, a carbamoyl, a carbamoyl substituted with an alkyl of 1 to 3 carbon atoms, an acetox, a carboxy, a hydroxy, an amino, an amino substituted with an alkyl of 1 to 4 carbon atoms, an alkyl or cycloalkyl of 1 to 10 carbon atoms, and an alkoxy or cycloalkoxy of 1 to 10 carbon atoms, or (ii) a phenyl substituted with 1 or more substituents each selected independently from the group consisting of an alkylidenemethyl of up to 10 carbon atoms, a cycloalkylidenemethyl of up to 10 carbon atoms, a phenyl, and a methylenedioxy; and **X** is -O- (applicant's claims 1 and 2, and claim 18), wherein **R2** is hydrogen, nitro, cyano, trifluoromethyl, amino, lower alkyl, lower alkoxy or halo (claim 3), wherein **R1** is alkyl of up to 10 carbon atoms and **R2** is hydrogen, trifluoromethyl, lower alkyl or lower alkoxy (claim 4 and claim 29), wherein **R1** is methyl or ethyl and **R2** is methoxy or ethoxy (claim 5) and wherein the compound is, for example, 3,3-bis-(3,4-dimethoxyphenyl)acrylonitrile and 3,3-bis-(3-ethoxy-4-methoxyphenyl)acrylonitrile (claim 7) are anticipated by claim 6 of US Patent No. 5,929,117 which discloses the compounds of, for example, 3,3-bis-(3,4-dimethoxyphenyl)acrylonitrile; 3,3-bis-(3-ethoxy-4-methoxyphenyl)acrylonitrile; 3-(3-



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propoxy-4-methoxyphenyl)-3-phenylacrylonitrile; 3-(3-ethoxy-4-methoxyphenyl)-3-phenylacrylonitrile; 3,3-bis-(3-cyclopentoxy-4-methoxyphenyl)acrylonitrile; 3-(3-cyclopentoxy-4-methoxyphenyl)-3-phenylacrylonitrile and 3-(3,4-dimethoxyphenyl)-3-phenylacrylonitrile.

Claims 1-7, 16-18, 27-29 and 38-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 6 and 11 of U.S. Patent No. 5,929,117. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants instant claims 1-5, 7, 18 and 29 are compound claims wherein **R1** is selected from the group consisting of any alkyl of up to 10 carbon atoms, any monocycloalkyl of up to 10 carbon atoms, any polycycloalkyl of up to 10 carbon atoms, and any benzocyclic alkyl of up to 10 carbon atoms; **R2** is hydrogen, nitro, cyano, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl, acetoxo, carboxy, hydroxy, amino, lower alkyl, lower alkoxy, or halo; **R3** is (i) phenyl unsubstituted or substituted with 1 or more substituents selected independently from the group consisting of a nitro, cyano, a halo, a trifluoromethyl, a carbethoxy, a carbomethoxy, a carbopropoxy, an acetyl, a carbamoyl, a carbamoyl substituted with an alkyl of 1 to 3 carbon atoms, an acetoxo, a carboxy, a hydroxy, an amino, an amino substituted with an alkyl of 1 to 4 carbon atoms, an alkyl or cycloalkyl of 1 to 10 carbon atoms, and an alkoxy or cycloalkoxy of 1 to 10 carbon atoms, or (ii) a phenyl substituted with 1 or more substituents each selected independently from the group consisting of an alkylidenemethyl of up to 10 carbon atoms, a cycloalkylidenemethyl of up to 10 carbon atoms, a phenyl, and a

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methylenedioxy; and X is -O- (applicants claims 1 and 2, in Z form only=claim 17, in E form only=claim 16 in racemate form=claim 18), wherein R2 is hydrogen, nitro, cyano, trifluoromethyl, amino, lower alkyl, lower alkoxy or halo (claim 3), wherein R1 is alkyl of up to 10 carbon atoms and R2 is hydrogen, trifluoromethyl, lower alkyl or lower alkoxy (claim 4, in E form=claim 27, in Z form=claim 28, in racemate form=claim 29), wherein R1 is methyl or ethyl and R2 is methoxy or ethoxy (claim 5), wherein the compound is 3-(3,4-dimethoxyphenyl)-3-(3',5'-dimethoxyphenyl)acrylonitrile (claim 6 in E form=claim 38, in Z form=claim 39 in racemate form=claim 40), wherein the compound is, for example, 3,3-bis-(3-4-dimethoxyphenyl)acrylonitrile and 3,3-bis-(3-ethoxy-4-methoxyphenyl)acrylonitrile (claim 7).

***Determining the scope and contents of the conflicting US Patent***

Claims 1 and 11 of US Patent No. 5, 929,117 claims a compound wherein X can be -O- and R1 is alkyl of up to 10 carbon atoms, monocycloalkyl of up to 10 carbon atoms, polycycloalkyl of up to 10 carbon atoms, or benzocyclic alkyl of up to 10 carbon atoms; R2 is hydrogen, nitro, cyano, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl, acetoxo, carboxy, hydroxy, amino, lower alkyl, lower alkylidenemethyl, lower alkoxy, or halo, R3 is (i) phenyl or naphthyl, unsubstituted or substituted with 1 or more substituents each selected independently from nitro, cyano, halo, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl or carbamoyl substituted with alkyl of 1 to 3 carbon atoms, acetoxo, carboxy, hydroxy, amino, amino substituted with an alkyl of 1 to 5 carbon atoms, alkyl of up to 10 carbon atoms, cycloalkyl of up to 10 carbon atoms, alkylidenemethyl of up to 10 carbon atoms,

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cycloalkylidenemethyl of up to 10 carbon atoms, phenyl or methylenedioxy; or (ii) cycloalkyl of 4-10 carbon atoms, unsubstituted or substituted with 1 or more substituents each selected independently from the group consisting of nitro, cyano, halo, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl, acetox, carboxy, hydroxy, amino, substituted amino, alkyl of 1 to 10 carbon atoms, alkoxy of 1 to 10 carbon atoms, and phenyl; each of R4 and R5 taken individually is hydrogen or R4 and R5 taken together are a carbon-carbon bond; Y is  $-\text{COZ}$ ,  $\text{C}=\text{N}$ , or lower alkyl of 1 to 5 carbon atoms, Z is  $-\text{OH}$ ,  $-\text{NR}_6\text{R}_6$ ,  $-\text{R}_7$ , or  $-\text{OR}_7$ ; R6 is hydrogen or lower alkyl; and R7 is alkyl or benzyl. Claim 2 claims the compound of the formula wherein R4 and R5 form a double bond, Y is CN and R3 is R3 is (i) phenyl or naphthyl, unsubstituted or substituted with 1 or more substituents each selected independently from nitro, cyano, halo, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl or carbamoyl substituted with alkyl of 1 to 3 carbon atoms, acetox, carboxy, hydroxy, amino, amino substituted with an alkyl of 1 to 5 carbon atoms, alkyl of or cycloalkyl of 1 to 10 carbon atoms, alkoxy or cycloalkoxy of 1 to 10 carbon atoms; or (ii) cycloalkyl of 4-10 carbon atoms, unsubstituted or substituted with 1 or more substituents each selected independently from the group consisting of nitro, cyano, halo, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl, acetox, carboxy, hydroxy, amino, substituted amino, alkyl of 1 to 10 carbon atoms, alkoxy of 1 to 10 carbon atoms, and phenyl. Claim 6 claims specific species, for example, 3,3-bis-(3,4-dimethoxyphenyl)acrylonitrile; 3,3-bis-(3-ethoxy-4-methoxyphenyl)acrylonitrile; 3-(3-propoxy-4-methoxyphenyl)-3-phenylacrylonitrile; 3-(3-

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ethoxy-4-methoxyphenyl)-3-phenylacrylonitrile; 3,3-bis-(3-cyclopentoxy-4-methoxyphenyl)acrylonitrile; 3-(3-cyclopentoxy-4-methoxyphenyl)-3-phenylacrylonitrile and 3-(3,4-dimethoxyphenyl)-3-phenylacrylonitrile.

***Ascertaining the differences between the conflicting US Patent and the claims at issue***

The difference between applicants' instant claims and the claims 1,2, 6 and 11 of US Patent No. 5,929,117 is that patent claim 1 claims compounds that generically overlap with applicants instant compounds as claimed. However, patent claims 2 and 11, which are dependent on patent claim 1, disclose preferences towards wherein X is – O- (patent claim 11) R4 and R5 are a double bond and Y is CN (patent claim 2) and patent claim 6, dependent on patent claim 2, claims species which are encompassed by applicants instant compound of the formula (I), for example 3,3-bis-(3-4-dimethoxyphenyl)acrylonitrile and 3,3-bis-(3-ethoxy-4-methoxyphenyl)acrylonitrile and example 10 of the patent, column 16 discloses the compound, 3-(3,4-dimethoxyphenyl)-3-(3',5'-dimethoxyphenyl)acrylonitrile, which corresponds to applicants instant further elected compound. Also, column 9 discloses that the compound invention encompasses and is preferred as the racemate isomers, (Z) isomer and the (E) isomer and discloses methods of separating the (Z) and (E) isomer from the racemate isomer

***Resolving the level of ordinary skill in the pertinent art***

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare compounds as instantly claimed when faced with claims 1-2, 6 and 11 of US Patent No. 5,929,117 since the claims are directed to products which generically overlap with applicants instantly claimed compounds (see patent claims 1-2 and 11), since claim 2 discloses preferences towards R4 and R5 forming a double bond

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and Y being CN, since claim 11 discloses preferences towards X being -O-, since claim 6 discloses further preferences to specific species within applicants instantly claimed products, for example, 3,3-bis-(3-4-dimethoxyphenyl)acrylonitrile and 3,3-bis-(3-ethoxy-4-methoxyphenyl) acrylonitrile, since example 10 of the patent, column 16 discloses the compound 3-(3,4-dimethoxyphenyl)-3-(3',5'-dimethoxyphenyl)acrylonitrile, which corresponds to applicants instant further elected compound and since column 12 discloses that the compound invention is in the form of the racemate isomer, (Z) and (E) form isomers and methods of separation. The motivation behind the obvious type double patenting would be to prepare other useful compounds for the treatment of conditions such as septic shock, cancer, autoimmune diseases, etc.

Claims 12, 23 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 5,929,117. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants instant claims 12, 23 and 34 are pharmaceutical composition claims which comprise the compounds of the formula (I) wherein **R1** is selected from the group consisting of any alkyl of up to 10 carbon atoms, any monocycloalkyl of up to 10 carbon atoms, any polycycloalkyl of up to 10 carbon atoms, and any benzocyclic alkyl of up to 10 carbon atoms; **R2** is hydrogen, nitro, cyano, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl, acetoxyl, carboxyl, hydroxyl, amino, lower alkyl, lower alkoyl, or halo; **R3** is (i) phenyl unsubstituted or substituted with 1 or more substituents selected independently from the group consisting of a nitro, cyano, a halo, a trifluoromethyl, a

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carbethoxy, a carbomethoxy, a carbopropoxy, an acetyl, a carbamoyl, a carbamoyl substituted with an alkyl of 1 to 3 carbon atoms, an acetoxyl, a carboxyl, a hydroxyl, an amino, an amino substituted with an alkyl of 1 to 4 carbon atoms, an alkyl or cycloalkyl of 1 to 10 carbon atoms, and an alkoxy or cycloalkoxy of 1 to 10 carbon atoms, or (ii) a phenyl substituted with 1 or more substituents each selected independently from the group consisting of an alkylidenemethyl of up to 10 carbon atoms, a cycloalkylidenemethyl of up to 10 carbon atoms, a phenyl, and a methylenedioxy; and X is -O- (applicants claim 1), wherein R1 is alkyl of up to 10 carbon atoms, R2 is hydrogen, trifluoromethyl, loweralkyl or lower alkoxy (claim 4) and wherein the compound is 3-(3,4-dimethoxy phenyl)-3-(3',5'-dimethoxyphenyl)acrylonitrile (claim 6).

***Determining the scope and contents of the conflicting US Patent***

Claim 5 of US Patent No. 5, 929,117 claims a pharmaceutical composition comprising the compound of the patent claim 1 wherein X can be -O- and R1 is alkyl of up to 10 carbon atoms, nonocycloalkyl of up to 10 carbon atoms, polycycloalkyl of up to 10 carbon atoms, or benzocyclic alkyl of up to 10 carbon atoms; R2 is hydrogen, nitro, cyano, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl, acetoxyl, carboxyl, hydroxyl, amino, lower alkyl, lower alkylidenemethyl, lower alkoxy, or halo, R3 is (i) phenyl or naphthyl, unsubstituted or substituted with 1 or more substituents each selected independently from nitro, cyano, halo, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl or carbamoyl substituted with alkyl of 1 to 3 carbon atoms, acetoxyl, carboxyl, hydroxyl, amino, amino substituted with an alkyl of 1 to 5 carbon atoms, alkyl of up to 10 carbon atoms, cycloalkyl of up to

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10 carbon atoms, alkylidenemethyl of up to 10 carbon atoms, cycloalkylidenemethyl of up to 10 carbon atoms, phenyl or methylenedioxy; or (ii) cycloalkyl of 4-10 carbon atoms, unsubstituted or substituted with 1 or more substituents each selected independently from the group consisting of nitro, cyano, halo, trifluoromethyl, carbethoxy, carbomethoxy, carbopropoxy, acetyl, carbamoyl, acetoxo, carboxy, hydroxy, amino, substituted amino, alkyl of 1 to 10 carbon atoms, alkoxy of 1 to 10 carbon atoms, and phenyl; each of R4 and R5 taken individually is hydrogen or R4 and R5 taken together are a carbon-carbon bond; Y is  $-\text{COZ}$ ,  $\text{C}=\text{N}$ , or lower alkyl of 1 to 5 carbon atoms, Z is  $-\text{OH}$ ,  $-\text{NR}_6\text{R}_6$ ,  $-\text{R}_7$ , or  $-\text{OR}_7$ ; R6 is hydrogen or lower alkyl; and R7 is alkyl or benzyl.

***Ascertaining the differences between the conflicting US Patent and the claims at issue***

The difference between the claims at issue and the patent claims of US Patent No. 5,929, 117 is that patent claim 5 is dependent on patent claim 1, which claims compounds that generically overlap with applicants instant compounds found in the pharmaceutical compositions. However, patent claims 2 and 11, which are dependent on patent claim 1, disclose preferences towards wherein X is  $-\text{O}-$  (patent claim 11) R4 and R5 are a double bond and Y is CN (patent claim 2) and patent claim 6, dependent on patent claim 2, claims species which are encompassed by applicants compound of the formula (I), for example 3,3-bis-(3,4-dimethoxyphenyl)acrylonitrile and 3,3-bis-(3-ethoxy-4-methoxyphenyl)acrylonitrile and example 10 of the patent, column 16 discloses the compound, 3-(3,4-dimethoxyphenyl)-3-(3',5'-dimethoxyphenyl)acrylonitrile, which corresponds to applicants instant further elected compound.

***Resolving the level of ordinary skill in the pertinent art***

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare pharmaceutical compositions as instantly claimed when faced with claim 5 of US Patent No. 5,929,117 since the claim is directed to pharmaceutical compositions which comprise compounds which generically overlap with applicants instant compounds of the formula (I), see patent claims 1 and 2, and since the claims provide preferences towards applicants instant formula (I) wherein X is -O- (patent claim 11) R4 and R5 are a double bond and Y is CN (patent claim 2) and furthermore, since claim 6 claims provides a further preference for specific species which are encompassed by applicants instant formula (I), for example 3,3-bis-(3-4-dimethoxyphenyl)acrylonitrile and 3,3-bis-(3-ethoxy-4-methoxyphenyl)acrylonitrile and since example 10 of the patent, column 16, a preference is disclosed for applicants further elected compound 3-(3,4-dimethoxyphenyl)-3-(3',5'-dimethoxyphenyl)acrylonitrile. The motivation behind the obvious type double patenting would be to prepare additional, useful pharmaceutical compositions for the treatment of conditions such as septic shock, cancer, autoimmune diseases, etc.

**Conclusion**


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

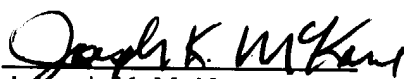



If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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